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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.   |
|---|-------------|----------------------|---------------------|--------------------|
| 10/729,648  | 12/05/2003  | Young Kweon Choi     | 428.1036            | 2815               |
| 22856   | 7590        | 03/23/2006           | EXAMINER            |                    |
| MUSERLIAN, LUCAS AND MERCANTI, LLP<br>475 PARK AVENUE SOUTH<br>NEW YORK, NY 10016 |             |                      |                     | KRASS, FREDERICK F |
| ART UNIT  |             | PAPER NUMBER         |                     |                    |
|   |             | 1614                 |                     |                    |

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/729,648             | CHOI ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Frederick F. Krass     | 1614                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 December 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/12/04.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

### **Claim Informalities**

The following informality is noted and should be corrected in responding to this Office action:

Claim 11, line 16, the last word on the line is spelled incorrectly and should in fact read --- sorbitan ---.

### **Specification**

The use of the trademarks "Eudragit", "Kollicoat" and "Dequest" has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### **Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 7, 8, 11, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 2, 7 and 8 contains the trademark/trade names “Eudragit” (L, L 100-55, and S grades) and “Kollicoat” (P and MAE grades); claim 11 contains the trademark/trade name “Dequest”. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe various polymers and phosphonates and, accordingly, the identification/description is indefinite.

2) Claim 13 is indefinite insofar as the bases for the percent calculations are not recited e.g., percent by weight of the polymer based on the total weight of the patch; based on the total weight of polymer complex; based on the weight of the adhesive or erosion rate-controlling layer individually, etc. See Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value

varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.)

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (WO 01/68045 A1) in view of Moro et al (USP 6,585,997 B2).

The primary reference discloses tooth whitening patches comprising a tooth adhesion layer and a backing layer.

The tooth adhesion layer comprises a hydrophilic polymer, or mixture of polymers, which may include poly alkyl vinyl ether-maleic acid copolymers, polyacrylic acid, and polyvinylpyrrolidone. See p. 11, lines 10-25. See also working example 6 at p. 21, in which the tooth adhesion layer contains a mixture of polyalkyl vinyl ether-maleic acid copolymer, polyvinyl pyrrolidone and hydrogen peroxide; as explained on p. 15, lines 30-34, the hydrogen peroxide forms a complex by hydrogen bonding with same. (Other peroxides may be used as well, e.g., tetrasodium pyrophosphate (see the first paragraph on p. 12)).

The backing layer comprises a film-forming polymer, or mixture of polymers, which may include various methacrylic copolymers including ethyl cellulose and Eudragit polymers (the L grades being specifically enumerated); see p. 17, lines 17-31; see also working example 1 at p. 19, in which the backing layer contains a mixture of ethyl cellulose and Eudragit.

Conventional additives may be included as well, e.g., peroxide stabilizing agents such as EDTA and sodium citrate (see the first paragraph on p. 14; see also the various working examples, e.g., working example 4 at p. 20); plasticizers such as propylene

glycol, glycerine and polyethylene glycol (p. 16, lines 16-21); and polyphosphates such as sodium hexametaphosphate (see the last paragraph on p. 16). Tooth whitening effect may be controlled by adjusting the result-effective variable of patch thickness (see the last paragraph on p. 9).

The primary reference thus differs from the instant claims insofar as it does not specifically disclose an erosion rate-controlling layer containing a mixture of a hydrophilic polymer and a film-forming polymer.

The secondary reference discloses transmucosal patches comprising an adhesive layer and an erosion rate-controlling backing layer. See col. 7, lines 39-49.

The adhesive layer is water-soluble and comprises a film-forming hydrophilic polymer and a bioadhesive polymer; the latter may be polyacrylic acid, polyvinylpyrrolidone, or a mixture of the two. (See col. 4, lines 1-7).

The erosion rate-controlling backing layer also comprises a film-forming hydrophilic polymer which is modified to be bioerodible by further incorporating a hydrophobic polymer. A preferred formulation includes hydroxypropyl methylcellulose in combination with at least one hydrophobic polymer selected from Eudragit polymers, ethylcellulose and methylcellulose, in combination with at least one hydrophilic polymer selected from the group consisting of polyvinylpyrrolidone, hydroxypropylmethylcellulose, hydroxyethylmethylcellulose, hydroxypropylcellulose, and polyvinylalcohol. (Col. 5, lines 3-11). Residence time may be controlled (thus providing optimal, tailored delivery of the active agent) by adjusting the result-effective

variables of polymer type and amount over a wide range (col. 4, lines 29-32), as well as the thicknesses of the individual layers (col. 12, lines 38-46).

The secondary reference thus differs from the instant claims insofar as it does not explicitly disclose use of a tooth whitening agent. It does, however, generally suggest the use of "any" active agent that has "desirable" effects (col. 5, lines 52-54).

It would have been obvious to have provided a backing layer in the primary reference tooth whitening patches which was erosion rate-controlling and bioerodible by adjusting the type and relative proportions of hydrophilic and hydrophobic polymers used therein, motivated by the desire to provide optimal, tailored delivery of the tooth whitening agent by controlling residence time as taught by the secondary reference. Similarly, it would have been obvious to have adjusted the thickness of each layer to provide optimal tooth whitening.<sup>1</sup> In doing so it would have been obvious to have arrived at the various polymer combinations and percentages specified by instant claims 3-8 and 13, as well as the particular thicknesses recited in instant claim 15, where the values for those result-effective variables (polymer type, polymer percentages, and layer thickness) were found to provide optimal performance by applying no more than routine experimentation.

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<sup>1</sup> This rationale is consistent with settled precedent which holds that, generally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable and/or optimal conditions generally involves the application of no more than routine skill in the art. In re Aller, 105 USPQ 233, 235 (CCPA 1955); see also In re Boesch, 205 USPQ 215 (CCPA 1980) and In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003). As discussed supra, the type and relative amounts of the polymers used in the various layers of tooth whitening patches are result-effective variables controlling erosion rate as taught by the secondary reference, as is layer thickness in controlling tooth whitening effect as taught by both the primary and secondary references.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300..

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

